

**Nicotine In Cigarettes And Smokeless Tobacco Products
Is A Drug And These Products Are Nicotine Delivery Devices Under
The Federal Food, Drug, And Cosmetic Act**

**U. S. Food and Drug Administration
Department of Health and Human Services
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PREFACE

The Food and Drug Administration (FDA) has conducted an extensive investigation and has engaged in comprehensive legal analysis regarding the agency's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. The results of that inquiry and analysis support a finding at this time that nicotine in cigarettes and smokeless tobacco products is a drug, and that these products are drug delivery devices within the meaning of the Food, Drug, and Cosmetic Act. Nonetheless, because the agency recognizes the unique importance of the jurisdictional issue as well as the factual justification for any proposed rule in this area, the agency invites comment on these matters. Comments submitted will receive full and serious consideration.

Elsewhere in the same issue of the Federal Register in which this document is published, the agency is issuing a proposed regulation of nicotine-containing cigarettes and smokeless tobacco products under the restricted device provisions of the Act. Comments should be sent to FDA's Dockets Management Branch and identified with the docket number 95N-0253J. Comments should be submitted by the date identified in the Federal Register.

Traditionally, the FDA has initiated enforcement actions in cases where the agency determines that a product is a drug or a delivery device. Because the agency has elected to embark on this initiative through rulemaking, no enforcement action will be brought pending completion of that process.

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7. Statement by David A. Kessler, M.D., Commissioner of Food and Drugs, on Nicotine-Containing Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, March 25, 1994
8. Statement by David A. Kessler, M.D., Commissioner of Food and Drugs, on the Control and Manipulation of Nicotine in Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, June 21, 1994
9. Remarks by David A. Kessler, M.D., Commissioner of Food and Drugs, The Samuel Rubin Program, the Columbia University School of Law, March 8, 1995
10. Additional Documents